

## REMARKS

Claim 43 has been corrected to fix a typographical error. Claim 43 had originally claimed hooks, not slits, but had been typed improperly by Applicants' attorney in the previous Response to Office Action. Thus, claim 43 has not been amended, but merely returned to its correct state. Claim 43 is therefore no longer a duplicate of claim 42.

## 35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added).

### Claims 38-59

Amended claim 38 claims an anastomosis system comprising “a unitary anastomosis device,” as well as “a holder tube configured to hold the unitary anastomosis device” and an expander “slidable with respect to the holder tube to a position at which at least part of the expander is positioned within the unitary anastomosis device and radially expands the unitary anastomosis device.” The unitary anastomosis device is now claimed positively.

In contrast, U.S. Pat. No. 6,193,734 to Bolduc (“Bolduc”) does not disclose each and every element of claim 38. For example, Bolduc does not disclose an anastomosis system that includes a unitary anastomosis device and an expander slidable to a position at which at least part of the expander is positioned within the unitary anastomosis device and radially expands the unitary anastomosis device. Rather, Bolduc discloses two separate embodiments of a system for performing anastomosis, neither one of which discloses each and every element of claim 38.

In the first embodiment, a plurality of separate, independent tissue securing members 14 are deployed with an applier member 16 that slides into a space between the individual tissue securing members (e.g., Figures 1-15; column 5, line 41 through column 9, line 37). Without admitting that the applier member 16 is an expander, it is assumed to be an expander for the purpose of this analysis. The independent tissue securing members may include ribs 36, such that “moving the applier member 16A toward the tissue structure T2...causes the end 20A of the applier member to drive against the rib 36A on each tissue securing member 14, which collapses the leg 30A of each member 14 against the wall of the second tissue structure T2.” (Figures 7-9; column 7, lines 51-56). Alternately, the ribs 36 are not present, and the applier member 16 terminates “in a bell-shaped end.” (e.g., Figures 3-4; column 5, lines 61-62). Motion of “the applier member 16...causes the bell-shaped end 20 of the applier member 16 to fold the first leg 30 of each tissue securing member 14 toward the second leg 32 and into contact with the wall of the second tissue structure T2.” (column 6, lines 59-64). Thus, motion of the applier member 16 relative to a plurality of separate, independent tissue securing members 14 causes those tissue securing members 14 to deploy. However, claim 38 claims an expander that “radially expands the unitary anastomosis device.” The tissue securing members 14 are separate and independent; they are not a unitary anastomosis device. Further, because they are separate and independent, they do not radially expand, but rather individually fold.

In the second embodiment, a plurality of hooks are connected to a hub. (e.g., Figures 16-30B; column 9, line 38 through column 13, line 51). Without admitting that the plurality of hooks connected to a hub is a unitary anastomosis device, such combination is assumed to be a unitary anastomosis device for the purpose of this analysis. Before deployment, “hooks 80 are biased from [a] first configuration to a second configuration” (column 10, lines 19-20) and maintained in the second configuration, “and possess a considerable amount of stored

energy due to their being manipulated from the first to the second configuration.” (column 10, lines 22-24, 34-37). The hooks are forced out of slots in an applier, and they are then “free to assume their first configuration...which results in the closed ends 82 of the hooks turning outward and clamping against the interior surface of the second tissue structure T2.” (column 11, lines 1-8). “The hooks 80 try to return to their unbiased configuration and in so doing exert considerable compressive force to sandwich the everted end E of the first tissue structure T1 between the hub 54 and the second tissue structure T2.” (column 11, lines 26-30). Thus, an expander is not used to radially expand the unitary anastomosis of Bolduc; rather, the hooks 80 of the unitary anastomosis device turn outward upon release from slots in the applier under the influence of stored energy within them. Bolduc discloses no expander or similar member for radial expansion of the unitary anastomosis device.

Thus, Bolduc does not disclose each and every element claimed in claim 38, and Applicants consequently believe claim 38 is in condition for allowance. Claims 39-59 are believed to be in condition for allowance as well under MPEP 608.01(n)(III).

In addition, the inherency rejection with regard to claims 46-48 is unsupported. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP 2112 (*citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (emphasis in original). In contrast, without providing a basis in fact or technical reasoning, the Office Action states summarily that “Bolduc’s anastomosis system inherently must have a handle that is connected to either the expander or the holder tube or both.” (Office Action, page 3). Further, without providing a basis in fact or technical reasoning, the Office Action states summarily that “as the handle is rotated, it must rotate both the expander and the holder tube.”

(Office Action, page 3). Thus, Applicants respectfully request that the rejection of claims 46-48 on the grounds of inherency be withdrawn.

**35 U.S.C. §103**

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

**Claims 45, 49**

Claims 47 and 48 each depend from independent claim 38. As discussed above, Bolduc does not teach or suggest all of the elements of claim 38. Because claims 47 and 48 depend from claim 38, claims 47 and 48 each include all the elements of claim 38. Thus, Bolduc neither teaches nor suggests all of the limitations of claims 47 and 48. Consequently, a *prima facie* case of obviousness has not been established, and Applicants believe that claims 48 and 49 are in condition for allowance under MPEP 608.01(n)(III).

Further, Applicants do not acquiesce in the statement in the Office Action that "it would have been obvious to one of ordinary art at the time the invention was made to modify the inventions of figures 3-5 and 10-12 [of Bolduc] to include the handle 88 as disclosed in figure 16 so that the expander/first member 16, 16B and the holder tube/second member 18, 18b can be longitudinally moved relative to one another." (Office Action, page 4). With

regard to claims 45 and 49, the Office Action expressly notes that Bolduc is “silent regarding the details of the handle.” (Office Action, page 3). Thus, Bolduc does not disclose all the limitations of claims 45-49, and no prima facie case of obviousness has been established. In addition, a lumen of an element cannot fairly be characterized as a “cam groove.”

Claims 60, 64-71, 84

Amended claim 60 claims a tool for deploying an anastomosis device, comprising “a first member configured to hold the anastomosis device; a second member, said first member and said second member threadlessly engaged with and slideable relative to one another, wherein relative motion of said first member and said second member causes deformation of the anastomosis device; and a handle connected to at least one of said first member and said second member, wherein rotation of said handle about an axis causes said first member and said second member to slide relative to one another.”

Amended claim 60 now expressly states that “said first member and said second member [are] threadlessly engaged with...one another.” In addition, claim 60 still claims a handle capable of rotation. In contrast, U.S. Pat. No. 6,485,496 to Suyker (“Suyker”) and U.S. Pat. No. 5,695,504 to Gifford (“Gifford”) do not teach or suggest all of the limitations of amended claim 60. As stated in the Office Action, Suyker “fails to disclose that the handle may be rotated.” (Office Action, page 4). Further, as stated in the Office Action, Gifford “discloses an anastomosis device deployment device wherein the rotation of a handle rotates threadedly engaged tubes relative to one another.” (Office Action, page 4).

Thus, neither Gifford nor Suyker, alone or in combination, teach or suggest all of the limitations of claim 60. Applicants believe independent claim 60 is in condition for allowance. Because claims 64-71 and 84 depend from claim 60, Applicants believe that they are in condition for allowance as well under MPEP 608.01(n)(III).

Claims 72, 76-83

The analysis performed above with regard to claim 60 applies equally here.

Applicants believe that independent claim 72 is in condition for allowance. Because claims 76-83 depend from claim 72, Applicants believe that they are in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Entry of this amendment and allowance of the pending claims are respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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